

REMARKS

In response to the Office Action mailed on October 4, 2006, Applicants amended claim 1, and added claims 44-47. Claims 1 and 43-47 are presented for examination.

The Examiner rejected claims 1 and 43 under 35 U.S.C. § 112, second paragraph, as being indefinite. As amended, claims 1 and 43 cover nanocrystalline materials including a metal selected from the group consisting of silver, platinum, and palladium; and an element selected from the group consisting of oxygen, nitrogen, carbon, boron, sulfur, a halogen, phosphorus, silicon, hydrogen, and combinations thereof. In particular, the Examiner stated that "it is unclear from this language whether the nanocrystalline material is a compound or complex of the metal and the element or a physical mixture of the metal and the element". (Office Action, page 2) Upon reading the specification, a person having ordinary skill in the art would readily understand that the nanocrystalline materials can be a compound, (see, e.g., published application, [0039]), the nanocrystalline materials can also be a physical mixture of the metal and the element such that the element is absorbed or trapped in the material. (See, e.g., *id.*, [0067]). Thus, claims 1 and 43 are not unclear, and Applicants request that the rejection of these claims be reconsidered and withdrawn.

The Examiner rejected claims 1 and 43 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. As amended, claims 1 and 43 cover methods of treating a subject having a condition by contacting an area of a subject having the condition with a nanocrystalline material, the nanocrystalline material includes a metal selected from the group consisting of silver, platinum, and palladium; and an element selected from the group consisting of oxygen, nitrogen, carbon, boron, sulfur, a halogen, phosphorus, silicon, hydrogen, and combinations thereof. The condition is inflammatory bowel syndrome. Upon reading Applicant's specification, a person having ordinary skill in the art would understand that inflammatory bowel disease is a mucosal or serosal condition, and certain mucosal or serosal conditions can be treated using a suppository and/or an enema. (See, e.g., *id.*, [0049]). A person having ordinary skill in the art would also understand that the metal-containing material can be in the form of an article, such as a tablet, that allows the article to pass through certain portions of

the gastrointestinal system with relatively little release of the metal-containing material, but that allows a relatively large amount of the metal-containing material to be released in a desired portion of the gastrointestinal system. For example, the article can be an enteric article such as an enteric tablet, the article can pass through the stomach with little metal-containing material being released, and the metal-containing material is then relatively easily released by the article in the intestines. (See, e.g., id., [0096]). Applicants also presented numerous examples of nanocrystalline materials in solution formulations, which can be used for contacting various mucosal or serosal areas in a body, and treatment is typically continued until therapeutic effects are no longer needed. (See, e.g., id., examples 7; and additional examples 4 and 7).

The Examiner also asserted that the state of the prior art shows an incomplete understanding of inflammatory bowel syndrome and cited numerous references. However, as disclosed in Silbermintz *et al.*, Inflammatory Bowel Diseases, Pediatrics Annals, Vol. 35(4), pages 269-274 (April 2006) ("Silbermintz"), numerous animal models suggests that abnormalities in an array of different genes that control various aspects of immune function, coupled with exposure of the intestine to luminal bacteria or chemical insults, result in the development of chronic intestinal inflammation. (See, e.g., Silbermintz, page 269, col. 2, lines 10-16). HCAPLUS abstract 2005:332256 discloses an antibacterial therapy that demonstrates promise for treatment of inflammatory bowel disease by both improving symptoms and causing disease remission. And HCAPLUS abstracts 2001:926257 and 2006:751551 both disclose that manipulation of the luminal content using antibiotics and/or probiotics represents a potentially effective therapeutic option, and that while results of antibiotic treatment in inflammatory bowel disease are controversial, this approach is frequently and successfully adopted in clinical practice. Therefore, despite an incomplete understanding of inflammatory bowel disease, antibiotic therapy can be successful in treatment, and an antibacterial compound such as a nanocrystalline material including silver, platinum, or palladium can be useful in the treatment of inflammatory bowel disease.

For at least these reasons, claims 1 and 43 are enabled. Therefore, Applicants request that the rejection of these claims be reconsidered and withdrawn.

Applicant : Gillis et al.
Serial No. : 10/690,724
Filed : October 22, 2003
Page : 6 of 6

Attorney's Docket No.: 14072-036001 / W 617

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: January 3, 2007

/Sean P. Daley/
Sean P. Daley
Reg. No. 40,978

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

21514357.doc